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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/034,621

12/21/2001

Walter Callen

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06/14/2005

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/034,621	Applicant(s) CALLEN ET AL.	
	Examiner Richard G. Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-12, 16, 17 and 28-55 is/are pending in the application.
- 4a) Of the above claim(s) 34, 35, 38 and 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 16, 17, 28-33, 36, 37, 39-43 and 45-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants amendment of claims 1, 4, 5, 9, 10, 12, 16, 17 and 45, 46 and 51-54 in the paper of 3/28/2005, is acknowledged. Claims 1-7, 9-12, 16, 17, 28-55 are still at issue and are present for examination.

Applicants' arguments filed on 3/28/2005, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 34, 35, 38 and 44 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

It is noted to applicants that applicants status identifier for claim 35 which is "(previously presented)" should be "(withdrawn)".

Claim Objections

Claims 46 is objected to because of the following informalities:

Claim 46 recites "...nucleic acid **comprising** encoding a polypeptide...". This should be amended such as "...nucleic acid **[[comprising]]** encoding a polypeptide..."

. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection was stated in the previous office action. For applicants convenience this rejection is repeated below.

Claims 50-54 are indefinite in there reference to the "active site of the polymerase". This is especially evident since applicants are using the reference to the "active site of the polymerase" as a means of structurally describing the claimed nucleic acids. It is unclear what applicants intend to be considered the "active site of the polymerase" as this phrase would be unclear to one of ordinary skill in the art, and thus the claims with this reference are unclear.

In response to this rejection, applicants have amended claims 50-54 and traverse the rejection on the basis that this amendment addresses this issue.

Applicants traversal and amendment are acknowledged, however, found nonpersuasive on the basis that applicants amendment has not addressed the issue. The rejection is based on the indefiniteness of "active site of the polymerase". Applicants amendment which recites "active site of the polymerase encoded by the nucleic acid" does not clarify what applicants intend to be considered the "active site of the polymerase".

Thus the rejection of claims 50-54 for being indefinite for the recitation of "active site of the polymerase" is maintained for the reasons previously stated.

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It is noted that in claim 16, the reference to “enzymatically active fragments of (a)” is interpreted as those fragments of (a) having polymerase activity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 and 50-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 17 and 50-54. In response to this previous rejection, applicants have amended claims 17 and 50-54 and traverse the rejection as it applies to the newly amended claims.

Claim 17 remains rejected under this statute, in spite of applicants amendment.

Applicants traverse the rejection of claim 17 on the basis that, as currently amended, claim 17 is directed to isolated or recombinant nucleic acid encoding a polypeptide having polymerase activity, wherein the polypeptide has a sequence comprising at least 30 consecutive amino acids of a polypeptide having a sequence as set forth in SEQ ID NO: 2 and that one of ordinary skill in the art would have been able to ascertain the scope of the claims with reasonable clarity and recognize that Applicants were in possession of the claimed invention at the time of filing. Applicants

submit that the structure of all of the species within the genus of claimed nucleic acids are sufficiently correlated to a particular known structure such that they can only comprise a subsequence of SEQ ID NO: 2 (at least 30 consecutive residues of SEQ ID NO: 2) and a function (polymerase activity).

Applicants further submit that applicants need not describe the claimed subject matter *in haec verba* to satisfy the description requirement, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that applicants invented the claimed subject matter.

Applicants complete argument has been considered but continues to be found nonpersuasive on the basis that the structural limitation of the claimed genus is insufficient to adequately describe the genus of claimed nucleic acids which encodes a mere 30 amino acids of the 803 amino acid sequence of SEQ ID NO: 2. Applicants claimed genus encompasses a virtually unlimited number nucleic acids encoding variations of the amino acid sequence of the disclosed polypeptide having the amino acid sequence of SEQ ID NO: 2.

Claims 50-54 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action. Specifically, the reference in newly added claims 50-54, (See also above 112 second paragraph rejection) which

recites "active site of the polymerase" and its use as a means of structurally describing the claimed polymerases is not supported by the specification at the time of filing. It was previously requested that applicants indicate where in the specification applicants have support for such a description of the claimed polymerases.

Applicants traverse this rejection on the basis that the term "active site of a polymerase" is sufficiently described by applicants specification and that one having ordinary skill in the art would recognize that applicants invented the claimed subject matter. Applicants specifically point to a number of paragraphs in the specification (i.e. page 67, lines 9 to 20, page 69, lines 23 to 27, page 53, lines 1 to 13) as support for the claimed subject matter.

Applicants complete argument is acknowledged, however, found non-persuasive on the basis that while it is believed that applicants do have literal support for the term "active site of a polymerase", applicants do not have support for the claimed subgenus of subject matter, specifically those nucleic acids wherein "the at least one conservative amino acid residue substitution does not occur at an active site of the polymerase". It is this claimed subgenus that applicants lack support for in the specification at the time of filing.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-7, 9-12, 17, 28-33, 36, 37, 39-43 and 45-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid comprising SEQ ID NO: 1 and encoding a polypeptide having polymerase activity, does not reasonably provide enablement for any nucleic acid comprising a mere 85% identity to SEQ ID NO: 1 and encoding a polypeptide having polymerase activity, or any nucleic acid encoding a mere 30 consecutive amino acids of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1-7, 9-12, 17, 28-33, 36, 37, 39-43 and 45-55. In response to this previous rejection, applicants have amended claims 1, 4, 5, 9, 10, 12, 16, 17 and 45, 46 and 51-54 and traverse the rejection of the newly amended claims.

Applicants continue to submit that the specification enabled the skilled artisan at the time of the invention to identify and make and use, a genus of polymerases to practice the claimed invention. In so doing, applicants reference the present amendment of the claims in which applicants have clarified that the claimed sequence itself must hybridize to the reference sequence (i.e. SEQ ID NO:1) and not a sub-sequence of the claimed nucleic acid sequence.

Further in support of applicants position applicants submit that the phrases used in the claims are used as "open-ended terms" and that applicants need not enable or describe "unrecited subject matter" as encompassed by the term "comprising".

Applicants amendment and traversal is acknowledged and is helpful in moving the claims towards allowable subject matter, however, the claims remain rejected on the basis that applicants have not enabled those nucleic acids comprising a mere 85% identity to SEQ ID NO: 1 and encoding a polypeptide having polymerase activity, or those nucleic acids encoding a mere 30 consecutive amino acids of SEQ ID NO: 2 and encoding a polypeptide having polymerase activity.

Applicants are again reminded that such a broadly defined genus, as that which encompasses those nucleic acids having a mere 85% sequence identity to SEQ ID NO: 1 and encode a polymerase, necessitates more guidance than is available to the skilled artisan in the art and applicants specification.

As previously stated, without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. While some guidance as argued by applicants' representative has been provided in the instant specification, such guidance is insufficient to enable those currently claimed nucleic acids which have a mere 85% identity to SEQ ID NO: 1.

Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity/function and the fact that the relationship between the sequence of a peptide

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and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those polypeptides of the claimed genus defined merely as all nucleic acids having at least 85% sequence identity to SEQ ID NO: 1 and encoding a polypeptide having polymerase activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including those nucleic acids comprising a sequence with the defined structural relationship to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal flourish extending to the right.

Richard G Hutson, Ph.D.

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Primary Examiner
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6/8/2005